DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 29, 2015

Saeshin Precision Co., Ltd.
Mr. Sae Kwan Choi
QA Manager
52, Secheon-ro 1-gil, Dasa-eup, Dalseong-gun
Daegu, 711-814
REPUBLIC OF KOREA

Re: K143411
Trade/Device Name: TRAUS ENDO
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: May 26, 2015
Received: May 28, 2015

Dear Mr. Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143411

Device Name

TRAUS ENDO

Indications for Use *(Describe)*

The TRAUS ENDO, ACL(B)-41EP, ACL(B)-42EP, and ACL(B)-45EP, are indicated for use by dentists in standard endodontic procedures using rotary files and rotary endodontic drills (Gates-Glidden).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K143411

510(k) Summary

[As required by 21 CFR 807.92]

This 510(k) summary is prepared in accordance with 21 CFR807.92

1. Date Prepared [21 CFR 807.92(a)(1)]

6/26/2015

2. Submitter's Information [21 CFR807.92(a)(1)]

- Name of Sponsor: Saeshin Precision Co., Ltd.
  - Address: # 52, Secheon-ro 1-gil, Dasa-eup, Dalseong-gun, Daegu, 711-814, Republic of Korea
- Contact Name: Sae Kwan, Choi (Mr.) / Quality Manager
  - Telephone No. : +82 53 587 2341
  - Fax No. : +82 53 580 0999
  - Email Address : ksqc@saeshin.com
- Registration Number: 3007958831
- Name of Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name: TRAUS ENDO
- Common Name: Dental Handpieces
- Classification Name: Dental Handpiece and Accessories
- Classification Panel: Dental
- Classification Regulation: 21 CFR 872.4200
- Product Code: EKX
- Device Class: I

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follows:

- 510(k) Number: K123582
- Applicant: Saeyang Microtech Co., Ltd.
- Common Name: Dental Handpieces
- Device Name: Endo a class

- 510(k) Number: K111616
- Applicant: Saeshin Precision Co., Ltd
- Common Name: Dental Handpieces
- Device Name: E-CUBE

K123582 is the primary predicate and K111616 is the reference predicate. There are no significant differences between the TRAUS ENDO dental handpieces and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in device design, composition of materials and technical specifications.

5. Description of the Device [21 CFR 807.92(a)(4)]

The TRAUS ENDO is an AC-powered device that includes a power unit, charging station and contra-angle handpieces, ACL(B)-41EP, ACL(B)-42EP and ACL(B)-45EP, are grinding, cutting, and polishing work in dental oral use.

6. Intended Use [21 CFR 807.92(a)(5)]

The TRAUS ENDO, ACL(B)-41EP, ACL(B)-42EP, and ACL(B)-45EP, are indicated for use by dentists in standard endodontic procedures using rotary files and rotary endodontic drills (Gates-Glidden).

7. Technological Characteristics [21 CFR 807.92(a)(6)]

- Model Nos. ACL(B)-41EP, ACL(B)-42EP and ACL(B)-45EP
- Gear Ratio: 20:1, 16:1, 32:1
- Dimensions: Ø 16.7 X 63 mm, Ø 16.7 X 63 mm and Ø 16.7 X 63 mm
- Weight: 34.8 g
- Charger: AC 100 – 240 V, 50 /60 Hz, DC 4.5V

One difference noted between the TRAUS ENDO and its predicates is its slower rotational speed, as a result of the 32:1 gear reduction ratio. However, equivalence to predicates has been demonstrated through bench testing and this difference raises no new concerns.

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Clinical Tests

A non-clinical evaluation, based on literature research, has been done. The evaluation of the applicable market data showed that TRAUS ENDO Dental handpieces, ACL(B)-41EP, ACL(B)-42EP and ACL(B)-45EP, do not pose known or new clinical risks than similar medical devices currently on the market. Based on those results clinical test have not been executed.

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8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

When compared to the predicate devices (K123582 and K111616), the subject device TRAUS ENDO has nearly identical:

- Intended Use
- Device Design
- Composition of materials
- Technical Specifications

The TRAUS ENDO is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed. The following tables outline the similarities and differences between the TRAUS ENDO and the predicate devices.

Parameter	**Proposed** **TRAUS ENDO**	**Predicate** **ENDO a class**	**Predicate** **E-CUBE**
510(k) Number	K143411	K123582	K111616
Manufacturer	Saeshin Precision Co., Ltd	Saeyang Microtech Co., Ltd.	Saeshin Precision Co., Ltd
Intended Use	TRAUS ENDO, ACL(B)-41EP, ACL(B)-42EP, and ACL(B)-45EP are indicated for use by dentists in standard endodontic procedures using rotary files and rotary endodontic drills(Gates-Glidden).	ENDO a class is indicated for application area extends to endodontic procedures using a root canal instrument which is intended by the manufacturer for use in mechanical and rotary preparation of root canals.	E-CUBE is indicated for use by dentists in standard endodontic procedures using rotary endodontic files and rotary endodontic drills(Gates-Glidden).
Device Design Components	Contra-Angle Handpiece Motor Handpiece Charging Station Power Cord	Contra-Angle Handpiece Motor Handpiece Charging Stand Motor Handpiece Cap Power Cord Oil Guide	Contra Box Micro Motor Contra-Angle Handpiece Foot-Control Pedal Adapter

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Parameter	Proposed TRAUS ENDO	Predicate ENDO a class	Predicate E-CUBE
Operational Mode	AC power and Gear driven	AC power and Gear driven	AC power and Gear driven
Reduction Ratio	16:1, 20:1, 32:1	4:1, 10:1, 16:1 and 20:1	1:1, 4;1, 10:1, 16;1, 20:1
Coupling Dimension	N/A	ISO 3964 connection	ISO 3964 connection
Chuck Type	Latch Type	Latch Type	Latch Type
Shank Type	Type 1	Type 1	Type 1
Composition of Materials			
Gear	Stainless steel (SUS420F)	Not Known	Stainless steel (SUS420F)
Shank	Stainless steel (Biodur Trimtite)		Stainless steel (Biodur Trimtite)
Head	Brass (C3604BD-F)		Brass (C3604BD-F)
Chuck	Stainless steel (SUS420F)		Stainless steel (SUS420F)
Handle	Aluminum (AL6061)		Aluminum (AL6061)
Patient-Contacting	Chuck, Head		Chuck, Head
Operator-Contacting	Handle, Head		Handle, Head
Technical Specification			
Supply Voltage	100-240 V AC 50/60 Hz	100-240 V	100-240 V AC 50/60 Hz
Operational Voltage	DC 4.5 V	DC 2.4 V	DC 4.5 V, 0.4 VA
Gear ratio	16:1, 20:1 and 32:1	4:1, 10:1, 16:1 and 20:1	1:1, 4:1, 10:1, 16:1 and 20:1
Torque	1 -4 Ncm	0.1 - 4.0 Ncm	0.6 – 5.2 Ncm
Motor Speed	100 – 12,000 rpm	140 – 500 rpm	1,000 – 13,000 rpm
Lubricant			
Chemical Composition 510k# Biocompatible Delivery system	N/A	N/A	K073353 (DO-ALL Dental handpiece Lubricant/ProDrive Systems Inc.)
Sterilization	Contra-angle at 132 ℃ for 4 minutes in Autoclave.	Contra-angle at 121 ℃ for 20 minutes or 132 ℃ for 15 minutes in Autoclave.	Contra-angle at 134 ℃ for 4 minutes in Autoclave.

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Parameter	Proposed TRAUS ENDO	Predicate ENDO a class	Predicate E-CUBE
Performance Standards			
IEC60601-1	Conform	Conform	Conform
IEC60601-1-2	Conform	Conform	Conform
ISO14457	Conform	Conform	Conform

9. Bench Testing

The following bench tests were performed on the TRAUS ENDO Dental Handpieces, ACL(B)-41EP, ACL(B)-42EP and ACL(B)-45EP, to verify conformity to standards and demonstrate substantial equivalence to the predicates:

- IEC 60601-1: Medical Electrical Equipment – Part 1 (2005/(R)2012 AND a1:2012)
- IEC 60601-1-2: Medical Electrical Equipment – Part 1-2 (2007-03)
- ISO 14457: Dentistry-Handpieces and Motors (2012-09-15)
- ISO 17665-1: Sterilization of health care products-Moist heat – Part1 (2006-08-15)
- ISO 1797-1: Shanks for rotary instrument – Part1 (1st edition Amendment)
- ISO 10993-1: Biological Evaluation of Medical Devices – Part 1 (4th Edition)

TRAUS ENDO Dental Handpieces, ACL(B)-41EP, ACL(B)-42EP and ACL(B)-45EP samples were compliant with standards and demonstrated substantial equivalence to the predicates.

10. Conclusion [21 CFR 807.92(b)(3)]

In accordance with the Federal Food, Drug and Cosmetic, 21 CFR Part 807, and based on the information provided in this premarket notification Saeshin Presicion Co., Ltd., we conclude that the TRAUS ENDO has been determined to be substantially equivalent to the predicate devices as described herein.